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#21

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Peter Forrest  
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Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,407,288

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,407,288, which claims the medical device CPI VENTAK PRx AICD System (an implantable cardioverter defibrillator and ventricular pacing system), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1107 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of November 15, 1994. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase)} + \text{Approval Phase} \\ &= 1/2 (398 - 0) + 908 \\ &= 1107 \text{ days}\end{aligned}$$

Since the regulatory review period began November 21, 1990, after the patent issue date (October 4, 1983), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) and the limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1107 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 4,407,288  
Granted: October 4, 1983  
Applicant: Alois A. Langer et al.  
Owner of Record: Mieczyslaw Mirowski  
Title: IMPLANTABLE HEART STIMULATOR AND STIMULATION METHOD  
Classification: 607/4  
Product Trade Name: CPI VENTAK PRx AICD System  
Term Extended: 1107 days

Gerald A. Dost  
Gerald A. Dost  
Senior Legal Advisor  
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Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

(703) 305-9285

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fisher's Lane, Room 11-44  
Rockville, MD 20857

RE: CPI VENTAK PRx AICD System  
FDA Docket No.: 94E-0315